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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,036	01/30/2002	Lloyd G. Simonson	06005.00001	8325

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/061,036

Applicant(s)

SIMONSON, LLOYD G.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 5 and 6 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: ____

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DETAILED ACTION

1. Claims 1-19 are pending and under consideration.

Specification

2. The disclosure is objected to because of the following informalities:
 - a) page 3, line 20, the reference Wilkinson et al is listed in its entirety. However, later, page 5, line 19, the reference is designated by the number (1). It is recommended that for consistency, only one method of designation be utilized,
 - b) page 14, line 16, the brief description states that Figure 3 is a "top" view, but it is a "side" view,

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is a method for detecting the presence of ≥ 1 predesignated, target antibody to a mycobacterium in a sample selected from one or more patient bodily fluids wherein the one or more bodily fluids is selected from a group of samples which include "culture media and other clinical and laboratory specimens and samples".

It is unclear how "culture media" or "other clinical and laboratory specimens and samples" are defined as a "patient bodily fluid".

6. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods and kits for detecting a target antibody to a mycobacterium utilizing a mycobacterium antigen which binds to said antibody, does not reasonably provide enablement for detection of an antibody to a particular mycobacterium species utilizing an antigen from any/all other species of mycobacterium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. .

The nature of the invention is a method and kit for detection of the presence of ≥ 1 predesignated, target antibody to a mycobacterium in a sample comprising contacting said sample with ≥ 1 mycobacterium antigen.

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The instant specification provides insufficient guidance and examples for the scope of the instant claims. The scope encompasses the detection of any/all antibodies to any/all mycobacterial species utilizing any/all antigens from any/all other mycobacterial species. For example, the specification does not teach how one detects antibodies to *M. scrofulaceum* using *M. tuberculosis* antigens or vice versa.

Therefore, the instant claims constitute merely an invitation to experiment without a reasonable expectation of success.

7. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are drawn to methods and kits for detection of a target antibody in a sample to a mycobacterium utilizing a mycobacterium antigen which binds to said antibody wherein said methods comprise: 1) contacting said sample with ≥ 1 mycobacterium antigen on a membrane in order for said antibody to bind to said antigen, 2) binding said antigen with a label producing a detectable signal, and 3) detecting the signal whereby the presence of the antibody is determined.

It is unclear how labeling the antigen detects the presence of the antibody, because the labeling is of the antigen, regardless of whether any antibody is bound or not. Thus, the detection of said signal would occur in both the presence or absence of said antibody.

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8. Claim 5 is objected to for the following informality: "mycobacterium tuberculosis" should be "*Mycobacterium tuberculosis*".

9. Claim 6 is objected for the following informality: "of" is missing between the words "mixture" and "two".


Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

June 30, 2003